

REMARKS

The above referenced application has been reviewed in light of the Office Action mailed May 21, 2009. Claims 1-23 are currently pending in this application. Claims 1, 15, and 21-23 have been amended by the response. It is respectfully submitted that the claims pending in the application are fully supported by the specification, introduce no new matter, and are patentable over the prior art. In view of the amendments and the remarks to follow, allowance of this application is respectfully requested.

Claims 1-7, 11, 12, 15-18, and 21-23 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,797,888 to Yoon (hereinafter, Yoon). Applicant respectfully submits that independent claims 1, 15, 21, 22, and 23 are each allowable over Yoon because Yoon fails to disclose each and every element of each of the independent claims. Accordingly, the rejection of claims 1, 15, 21, 22, and 23 as being anticipated under 35 U.S.C. §102(b) over Yoon is respectfully traversed.

According to §2131 of the MPEP, to anticipate a claim, the reference must teach each and every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

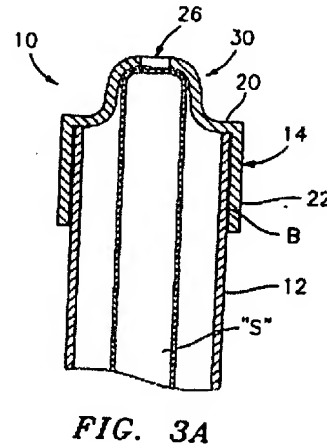
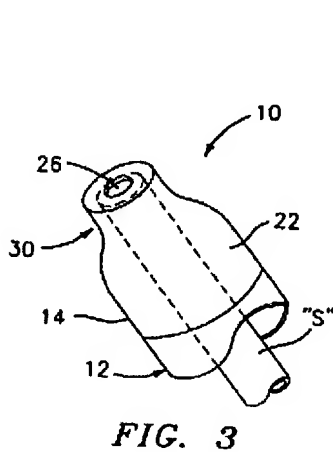
Independent claim 1 recites, in pertinent part, a surgical instrument and instrument introducer assembly comprising, *inter alia*, a surgical instrument for performing a surgical procedure and an instrument introducer assembly including a tubular body portion and a distal end portion secured to the distal end of the tubular body portion, the distal end portion defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is

substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument therethrough in a sealing relation to the surgical instrument, wherein the surgical instrument stretches the distal end portion of the instrument introducer as it is advanced therethrough.

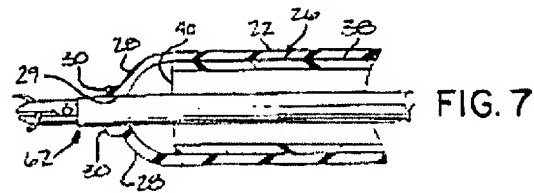
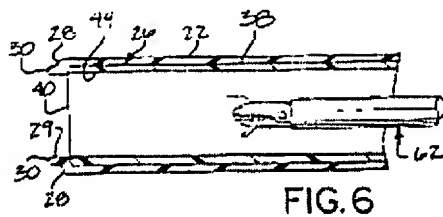
Support for the amendments to the claim is provided throughout the specification. For example, page 6, lines 10-12 of the specification states that the “device according to the present disclosure can be used in connection with other surgical instruments for performing any number of other endoscopic or laparoscopic surgical procedures.” Page 10, lines 1-21 of the specification describes “pocket 30 stretches/flexes distally and through-hole 26 stretches/flexes radially outward to a diameter sufficient to accommodate the passage of smaller diameter surgical instrument “S” therethrough” when a smaller diameter surgical instrument is advanced through the instrument introducer and “pocket 30 stretches/flexes to conform to the shape of the distal end of the larger diameter surgical instrument” when a larger diameter surgical instrument is advanced therethrough. Page 4, lines 8-9 of the specification states that “the cap [secured to the distal end of the tubular body] creates a seal around the perimeter of the surgical instrument extending therefrom.”

An exemplary illustration of an embodiment of the present application is shown in Figures 3 and 3A, reproduced herein below. The distal end portion defines a pocket 30 including a substantially planar distal end wall configured and adapted to stretch and conform to the shape of the surgical instrument to facilitate passage of the surgical instrument therethrough in a

sealing relation to the surgical instrument. As illustrated and described in the specification, the distal end wall remains in contact with an outer surface of the surgical instrument "S" as the surgical instrument is advanced therethrough and stretches the instrument introducer.



Yoon discloses a cannula 20 including an elongated tubular body 22, a seal 24 including a seal member 28 disposed along the tubular body 22, and a tubular pusher 26 disposed in the tubular body 22 and insertable through the seal 24 to move the seal member 28 from a normally closed position to an open position. As shown in Figure 6 of Yoon, reproduced herein below, lips 30 formed by seal members 28 are opened by longitudinally moving the cylindrical body 38 of tubular pusher 26 into the passage defined by seal member 28. The pusher 26, which is separate from the instrument 62, overcomes the closing force or bias of the seal members 28 and spreads the seal members 28 apart. The separate instrument 62 (for operating on tissue) is then inserted through the pusher 26 distally of seal 24, whereafter the pusher 26 is retracted, as shown in Figure 7 of Yoon, so that the seal 24 is no longer held in an open position but is engaged with the instrument 62 to form a seal therewith along lips 30 and the distal edges of seal member 28.



Moreover, Yoon specifically discloses that “a further object of the present invention is to bias a seal to a normally closed position along the tubular body of a cannula while permitting introduction and withdrawal of instruments through the cannula *without the instruments contacting the seal.*” (Emphasis added, Col. 2, lines 24-28). As described above, it is the tubular pusher, and not the surgical instrument for performing the surgical procedure, which contacts the seal and opens the seal member and accordingly, the distal end wall of Yoon is not configured and adapted to stretch and conform to the shape of the surgical instrument to facilitate passage of the surgical instrument in a sealing relation, wherein the surgical instrument stretches the instrument introducer as it is advanced therethrough.

Therefore, Applicant respectfully submits that Yoon fails to anticipate each and every element of claim 1. Accordingly, since Yoon does not disclose or suggest each and every element of claim 1, Applicant respectfully submits that the rejection of claim 1 as being anticipated under 35 U.S.C. §102(b) in view of Yoon should be withdrawn.

Since claims 2-7, 11, and 12 depend, directly or indirectly, from claim 1 and contain all of the limitations of claim 1, Applicant respectfully submits that claims 2-7, 11, and 12 are also not anticipated under 35 U.S.C. §102(b) over Yoon.

Independent claim 15 recites, in pertinent part, a surgical instrument and instrument introducer assembly comprising, *inter alia*, a surgical instrument for performing a surgical

procedure and an instrument introducer assembly including a hollow elongate cylindrical body and an elastomeric cap secured to the distal end portion of the cylindrical body, the cap defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket, the distal end wall including an aperture formed in the pocket configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument therethrough in a sealing relation to the surgical instrument, wherein the surgical instrument stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough.

Since claim 15 requires that the surgical instrument stretches the aperture and/or contacts the introducer, similar to claim 1, for at least the reasons that claim 1 is allowable over Yoon, Applicant submits that claim 15 is also allowable over Yoon. Therefore, Applicant respectfully submits that the rejection of claim 15 under 35 U.S.C. §102(b) in view of Yoon should be withdrawn.

Since claims 16-18 depend, directly or indirectly, from claim 15 and contain all of the limitations of claim 15, Applicant respectfully submits that claims 16-18 are also not anticipated under 35 U.S.C. §102(b) over Yoon.

Independent claims 21 and 22 both recite, in pertinent part, a method of introducing a surgical instrument into a cavity or a body opening of a patient, comprising, *inter alia*, the steps of providing a surgical instrument for performing a surgical procedure, providing an instrument introducer assembly, and advancing the surgical instrument through the lumen of the tubular body of the instrument introducer thereby stretching the instrument introducer such that the

aperture of the distal end wall stretches and conforms to a shape of the outer surface of the surgical instrument until the distal end of the surgical instrument projects out through the aperture of the cap, wherein the cap creates a seal around the perimeter of the surgical instrument extending therefrom.

Since claims 21 and 22 also require that the surgical instrument stretches the instrument introducer and/or contacts the introducer, similar to claim 1, for at least the reasons that claim 1 is allowable over Yoon, Applicant submits that claims 21 and 22 are also allowable over Yoon. Therefore, Applicant respectfully submits that the rejection of claims 21 and 22 under 35 U.S.C. §102(b) in view of Yoon should be withdrawn.

Independent claim 23 recites, in pertinent part, a surgical instrument and instrument introducer assembly comprising, *inter alia*, a surgical instrument for performing a surgical procedure and an instrument introducer assembly including a tubular body portion defining a lumen therethrough and a distal end portion secured to the distal end of the tubular body portion, the distal end portion defining a pocket including a substantially circular distal end wall and an annular wall depending from the circular distal end wall to the tubular body portion, wherein the annular wall is configured and adapted to contact an outer surface of the surgical instrument and facilitate passage of the surgical instrument therethrough, wherein the distal end wall of the distal end portion includes an aperture formed therein configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument in a sealing relation to the surgical instrument, wherein the surgical instrument stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough.

Since claim 23 requires that the surgical instrument stretches the instrument introducer and/or contacts the introducer, similar to claim 1, for at least the reasons that claim 1 is allowable over Yoon, Applicant submits that claim 23 is also allowable over Yoon. Therefore, Applicant respectfully submits that the rejection of claim 23 under 35 U.S.C. §102(b) in view of Yoon should be withdrawn.

Claims 1-13, 15-19, and 23 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,792,074 to Turkel et al. (hereinafter, Turkel). Applicant respectfully submits that independent claims 1, 15, and 23 are allowable over Turkel because Turkel fails to disclose each and every element of the independent claims as required under 35 U.S.C. §102(b). Accordingly, the rejection of claims 1, 15, and 23 as being anticipated under 35 U.S.C. §102(b) over Turkel is respectfully traversed.

In contrast to amended independent claim 1, Turkel discloses a protected microbiological sampling brush assembly 10 including a sampling brush 12, an inner catheter 18 which houses the brush 12, an outer catheter 22 which houses the inner catheter 18, and an elastomeric tip 24 which is rigidly attached to the distal end 22a of the outer catheter 22 and which has a weakened end defining lips 26. “[T]he inner catheter 18 is slightly longer than the outer catheter 22 and has a smaller outer diameter so that it can traverse the lumen of the outer catheter.” (Col. 4, lines 44-47). As shown in Fig. 4 of Turkel, reproduced below, lips 26a and 26b are parted by contact with distal end 18a of catheter 18 and thus, only the edge of lips 26a and 26b of tip 24 are in contact with the outer surface of catheter 18. Sampling brush 12 may be moved in and out of distal end 18a of inner catheter 18.

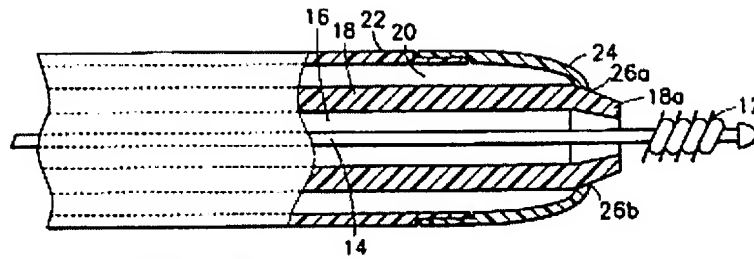


FIG. 4

Applicant respectfully submits that Turkel fails to anticipate each and every element of claim 1, in that Turkel fails to disclose a pocket including a substantially planar distal end wall configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument in a sealing relation to the surgical instrument, wherein the surgical instrument stretches the distal end portion of the instrument introducer as it is advanced therethrough.

Accordingly, since Turkel does not disclose or suggest each and every element of claim 1, Applicant respectfully submits that the rejection of claim 1 as being anticipated under 35 U.S.C. §102(b) in view of Turkel should be withdrawn.

Since claims 2-13 depend, directly or indirectly, from claim 1 and contain all of the limitations of claim 1, Applicant respectfully submits that claims 2-13 are also not anticipated under 35 U.S.C. §102(b) over Turkel.

Since claim 15 requires that the surgical instrument stretches the instrument introducer and/or contacts the introducer, similar to claim 1, for at least the reasons that claim 1 is allowable over Turkel, Applicant submits that claim 15 is also allowable over Turkel. Accordingly, Turkel fails to teach or disclose a pocket configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument

therethrough in a sealing relation to the surgical instrument, wherein the surgical instrument stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough. Therefore, Applicant respectfully submits that the rejection of claim 15 under 35 U.S.C. §102(b) in view of Turkel should be withdrawn.

Since claims 16-19 depend, directly or indirectly, from claim 15 and contain all of the limitations of claim 1, Applicant respectfully submits that claims 16-19 are also not anticipated under 35 U.S.C. §102(b) over Turkel.

Since claim 23 requires that the surgical instrument stretch the instrument introducer and/or contacts the introducer, similar to claim 1, for at least the reasons that claim 1 is allowable over Turkel, Applicant submits that claim 23 is also allowable over Turkel. Accordingly, Turkel fails to teach or disclose the distal end wall of the distal end portion including an aperture formed therein configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument in a sealing relation to the surgical instrument, wherein the surgical instrument stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough. Therefore, Applicant respectfully submits that the rejection of claim 23 under 35 U.S.C. §102(b) in view of Turkel should be withdrawn.

Claims 14 and 20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of U.S. Patent Appl. No. 2002/0099258 to Staskin et al. (hereinafter, Staskin). Applicants respectfully submit that Yoon and Staskin, either alone or in combination, fail to teach or suggest the claimed apparatus.

As stated above, Yoon fails to disclose, among other things, a pocket including a substantially planar distal end wall configured and adapted to stretch and conform to a shape of

the outer surface of the surgical instrument to facilitate passage of the surgical instrument in a sealing relation, wherein the surgical instrument stretches the instrument introducer as it is advanced therethrough, as called for in claims 1 and 15.

Staskin fails to cure the deficiencies in Yoon. Staskin discloses a sling device including a needle, a dilator, and a sling material for treating urological disorders. The dilator may have different profiles, such as frusto-conical. Nowhere does Staskin disclose or suggest an instrument introducer having a distal end portion defining a pocket including a substantially planar distal end wall configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument in a sealing relation, wherein the surgical instrument stretches the instrument introducer as it is advanced therethrough.

Therefore, the prior art references, taken in any proper combination, do not teach or suggest, as a whole, all of the claim limitations of claims 14 and 20 as claims 14 and 20 depend from independent claims 1 and 15, respectively, and contain all of the features of the claims. For at least these reasons, *inter alia*, Applicant believes that claims 14 and 20 define over Yoon and Staskin and are in condition for allowance. Therefore, Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) has been overcome.

In view of the foregoing amendments and remarks, Applicants submit that all of the claims are in proper format and are patentably distinct from the prior art of record and are in condition for allowance. The Examiner is invited to contact the undersigned at the telephone number listed below with any questions concerning this application.

Early and favorable response on the merits is earnestly solicited.

Respectfully submitted,



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